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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 111

[Docket No. 96N-0417].

Dietary Supplements; Center for Food Safety and Applied Nutrition; Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public meetings.

SUMMARY: The Food and Drug Administration (FDA) is announcing two public meetings to solicit comments that will assist the Center for Food Safety and Applied Nutrition (CFSAN) to understand the economic impact that any proposal to establish current good manufacturing practices (CGMP) regulations for dietary supplements may have on small businesses in the dietary supplement industry. These meetings are intended to give interested persons, including small businesses, an opportunity to comment on the economic impact that such a proposal may have on small businesses.

DATES: The public meetings will be held on Tuesday, September 28, 1999, from 1 p.m. to 5 p.m. and Thursday, October 21, 1999, from 7 p.m. to 10 p.m. You should register at least 5 days prior to the meeting you will attend. You may submit written comments until November 21, 1999.

ADDRESSES: The public meeting on September 28, 1999, will be held at the Marriott Hotel, 75 South West Temple, Wasatch Room, Salt Lake City, UT 84101. The public meeting on October 21, 1999, will be held at the Holiday Inn-Inner Harbor, 301 West Lombard St., Baltimore, MD 21201. Submit written comments to the Dockets Management Branch (HFA-305), Docket No. 96N-0417, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any comments are to be submitted, except that individuals may submit one copy.

FOR FURTHER INFORMATION CONTACT: Peter J. Vardon, Center for Food Safety and Applied Nutrition (HFS-726), Food and Drug Administration, 330 C St. SW., Washington, DC 20204, 202-205-5329, FAX 202-260-0794, or e-mail pvardon@bangate.fda.gov.

SUPPLEMENTARY INFORMATION: These public meetings will provide an opportunity for an open discussion of the manufacturing practices of small businesses in the dietary supplement industry. These meetings are intended to provide interested parties an opportunity to comment on the economic effects of a possible proposed regulation on CGMP's in the dietary supplement industry. These public meetings are also intended to fulfill part of the outreach requirement of the Small Business Regulatory Enforcement Fairness Act of 1996. The agenda will include topics regarding the small business entities' manufacturing practices and standard operating procedures for: (1) Personnel; (2) buildings and facilities; (3) equipment; (4) laboratory operations; (5) production and process controls; and (6) warehousing, distribution and post-distribution of raw, intermediate and final products. The meeting will also include a discussion about the verification of the identity, purity, and composition of dietary supplements and dietary supplement ingredients.

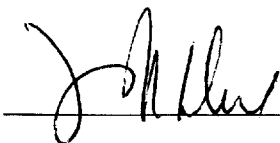
If you would like to attend a public meeting, you should register at least 5 days prior to the meeting by faxing or e-mailing your name, title, firm name, address, and telephone number to Peter J. Vardon (address above). FDA encourages individuals or firms with relevant data or information to present such information at the meeting or in written comments to the record. If you would like to request to speak at these meetings, you may notify Peter J. Vardon (address above) when you register. There is no registration fee for these public meetings, but early registration is suggested because space may be limited.

You may request a transcript of the public meeting from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857,

approximately 15 working days after the meeting. The transcript of the public meeting and submitted comments will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p. m., Monday through Friday.

Dated: 8/27/99

August 27, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

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